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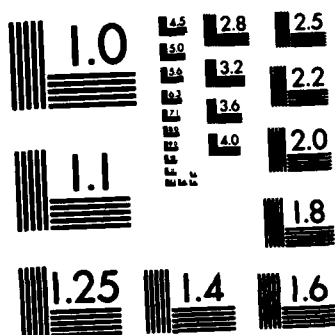
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REPORT NUMBER 11

SURGICAL TOOTH IMPLANTS, COMBAT AND FIELD

Annual Report

Craig R. Hassler, Robert H. Downes,
and Larry G. McCoy

July 1981

Supported by

U. S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
Fort Detrick, Frederick, Maryland 21701

Contract No. DADA-17-69-C-9181

BATTELLE
Columbus Laboratories
505 King Avenue
Columbus, Ohio 43201

DOD AVAILABILITY STATEMENT

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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Long term implant studies of alumina tooth roots are being performed in both humans and baboons. The implants designed for this project are a single root rectangular design with serrations arranged for maximal stress distribution of occlusal loads. The implant is of a three-piece design. The serrated root portion is alumina ceramic. The upper two parts of the implant (post and core and crown) are conventional dental materials, usually gold.		

Roots are produced by grinding bisque fired alumina stock on a computer controlled milling machine. This technique provides high quality, high strength, and design flexibility. A series of nineteen graded sizes of implants have been produced. In the last year design modifications and improved fabrication techniques have allowed the production of roots as small as 4 mm x 4 mm in cross section. Serration depth was selectively reduced in smaller implants to provide for the necessary bulk of ceramic. Extensive quality assurance has been performed on the implants intended for human use. Quality assurance procedures include: wet densities, visual inspection and mechanical testing of test bars. Modification of post and core design and its effect upon overall implant strength were evaluated.

Long term implants are being followed in the baboon colony. "Success" rate continues high, similar to that reported in the previous year. A total of 4 of 34 roots have fractured after an average implant life of 74 weeks. With baboons, the longest time of success in function is approaching 6 years. The human implant study has been underway since fall of 1978. To date, 39 patients have been implanted, 24 patients have been reconstructed. The clinical course can be similar to the baboon in the human. However, the human studies have not been as successful as the animals. The technique of implantation appears to be more critical in the human. Three different approaches to initial stabilization have been attempted. The most critical period for failure of roots is during the initial 3-month ingrowth period. This ingrowth period is most crucial to the overall success of the implant without some degree of stabilization, long term function is questionable. At this time, implantation of the root flush with the alveolar crest, appears to be the most promising approach.

It is intended that the animals and patients in this study be followed as long as possible so that the true long-term effects of such an implant system can be adequately evaluated.

FOREWORD

This study has been conducted at Battelle's Columbus Laboratories utilizing the staff and resources of the Health and Environmental Sciences Section and the Ceramics Section. The clinical portion of this study has been conducted at The Ohio State University College of Dentistry.

This is the eleventh report on progress under Contract No. DADA-17-69-C-9181, "Surgical Tooth Implants, Combat and Field". The principal investigator for this research was Dr. Craig R. Hassler. Ceramics research was directed by Mr. Larry G. McCoy. The human studies have been under the direction of Dr. Robert H. Downes and have been conducted in the clinical facilities of the College of Dentistry. Clinical research was conducted under a protocol approved by The Ohio State University human subjects committee. This research has been performed in accordance with an investigational device exemption obtained from the FDA. Animal research, conducted at Battelle Columbus has followed the guidelines of the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (DHEW Publication No. (NIH) 78-23, Revised 1978).

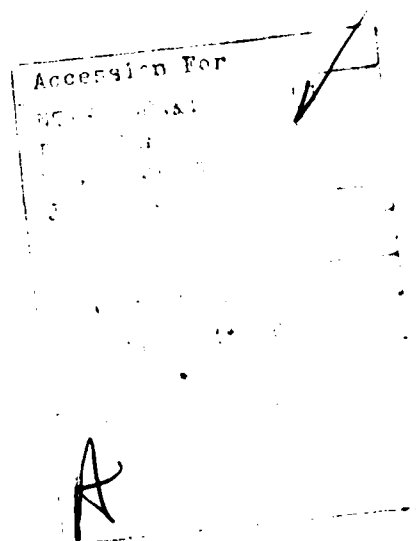


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SURGICAL TOOTH IMPLANTS, COMBAT AND FIELD

by

Craig R. Hassler, Robert H. Downes, and Larry G. McCoy

BACKGROUND

In the last several years a new generation of dental implants has evolved. These devices are designed to be rigidly affixed by bone ingrowth and provide minimization of stress usually by serrations⁽¹⁻⁴⁾ or pores.⁽⁵⁻⁶⁾ Generally, these implants are designed as single freestanding prostheses. Several biocompatible materials have been utilized including plastics,⁽⁷⁾ metallics⁽⁶⁾, and ceramics.^(1,2,3,8-18,22-24,26-29) Our laboratory has specialized using alumina (Al_2O_3) ceramics incorporating a serrated design. In the past 10 years we have evolved a combination of material, design, and technique components which appear promising. It should be noted that all three components (design, material and technique) are of importance if an implant system is to be successful. Failure of any of the three can be detrimental. A serrated ceramic implant system based upon these principles is under test in our laboratories. Implant experience in animals exceeds 5 years of function. On the strength of the animal experiments, a clinical study was undertaken to evaluate how much of the technology was relevant to the human situation.

The lower portion of our three-piece implants are produced from alumina (Al_2O_3) (Figure 1). This portion has large serrations into which bone ingrowth has been demonstrated.⁽⁴⁾ A variation of the implant illustrated in Figure 1 has smaller serrations at the crown end of the root to increase the strength of smaller sized roots in these critical areas. The upper two portions of the implant: post and core and crown - are cemented after ingrowth to allow function. The three-piece design allows minimization of occlusal stresses on the implant to facilitate bone ingrowth. An analogous situation is seen in the healing of long bone. It is assumed that as in long bone an orderly transition through a sequence of gradually stiffer bone materials proceeds (hematoma connective tissue woven bone compact bone). The maximal strain which any of these tissues can withstand must not be exceeded if healing is to proceed to completion.⁽²¹⁾ Consequently, strain upon the implant-bone interface must be minimized early in the healing process if bone formation is to occur. Once the implant is stabilized by ingrowth, the large implant surface area at right angles to the principal load axis of the implant is intended to maintain bone stresses below a level which produces resorption of bone. Attempts to quantify these stresses have been made in this laboratory.⁽⁹⁾ This information is not specifically for alveolar bone. However, it serves as a guide in an area where no direct information is available. As demonstrated by histologic data collected on this project⁽²⁾, the hypothesis appears to be viable and bone can exist successfully in direct contact with a functional implant.

The above mentioned parameters, unique to this design, are the serrations and three piece construction. They are the two major determinants

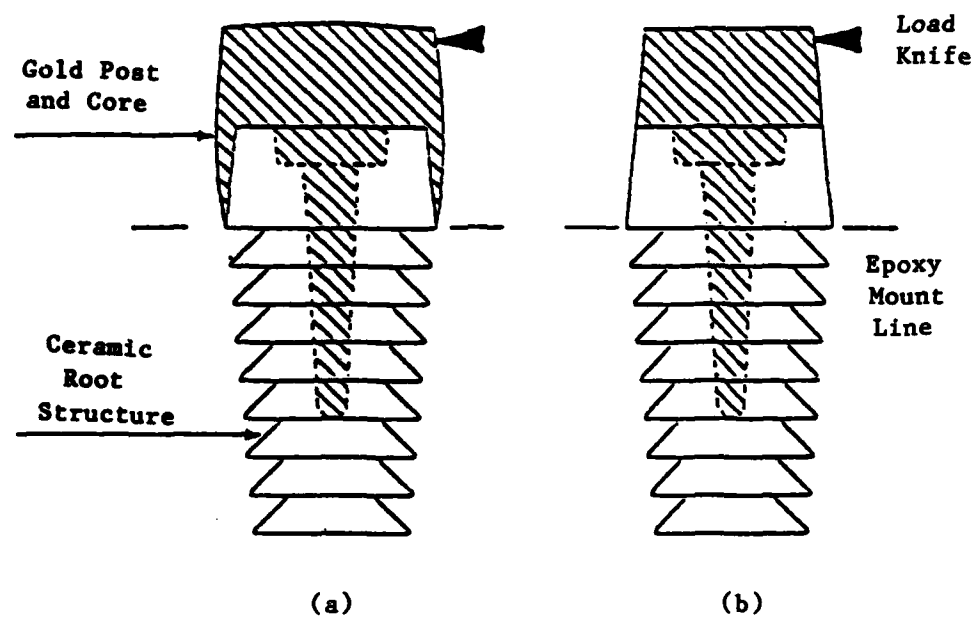


FIGURE 1. POST DESIGNS FOR CERAMIC ROOT STRUCTURES
(a) OVERLAP DESIGN, (b) FLUSH DESIGN

for design success. A secondary design parameter which has proven useful is the use of a size graded series of implants. This gradation allows optimal fit into the available site. Nineteen sizes have been produced for the clinical studies. In practice several of these sizes are not used but they are available when required. Both rectangular and elliptical implants were used in baboons. However, the rectangular shape appeared to provide a better initial fit. Consequently, this design is being used exclusively in clinical trials. The method of producing roots by contour grinding on a computer controlled milling machine has allowed for flexibility not only in size but in other design changes. In a research protocol, this ease of flexibility has been an asset and will continue to be our method of root manufacture.

At this time, the long term animal success is encouraging. Success for a similar or longer time span in humans is necessary to determine the true success of the implant.

METHODS

Fabrication of Tooth Roots

The objective of this year's effort was to fabricate 90 to 100 implants of the sizes shown in Table 1. The fabrication was to be divided into two equal size batches using the remaining powder from the previous fabrication effort and newly acquired and characterized powder from the same manufacturer. This approach was taken to conserve powder and to verify the reproducibility of the processing. The powder used was Reynolds Aluminum Company's RC-HP-DBM. This is a high purity dry ball milled powder having a median particle size of approximately 0.5 microns. The vendor data for the two powders are summarized in Table 2 and are generally found to be accurate. The most recent powder has slightly lower purity but is finer, has a higher surface area, and a higher pressed and sintered density under the same conditions.

TABLE 1. TOOTH ROOT SIZES (millimeters)

4 x 4 x 15	5 x 5 x 15	6 x 6 x 15	7 x 7 x 15
4 x 5 x 15	5 x 6 x 15	6 x 7 x 15	7 x 8 x 15
4 x 6 x 15	5 x 7 x 15	6 x 8 x 15	7 x 9 x 15
4 x 7 x 15	5 x 8 x 15	6 x 9 x 15	

The remaining original powder had been previously prepressed and granulated and had remained on the shelf for approximately 1 year. The processing procedure used was as follows:

- (1) Hydrostatic pressing the raw alumina powder at 10,000 psi
- (2) Granulation by crushing the pressed shapes to pass a 40-mesh screen
- (3) Hydrostatic pressing granulated material at 50,000 psi to form preform rods nominally 125 mm long by 14 mm diameter
- (4) Bisque firing preform rods at 1120 C for 2 hours
- (5) Contour grinding tooth roots
- (6) Hand finishing tooth roots
- (7) Final sintering at 1540 C for 1-1/2 hours.

TABLE 2. ALUMINA POWDER DATA

Material Designation	Sample No.	Alk	MgO	Purity SiO ₂	Metals	Particle Size % < 1
RC-HP-DBM (3-15-78, Lot 1)	--	.024	.045	.016	.016	83.3
RC-HP-DBM (8-15-80, Lot 2)	80-314	.026	.050	.018	.016	89.3

Surface Area m ² /gm	Pressed Density ^(a) gm/cm ³	Sintered Density ^(b) gm/cm ³	Shrinkage Percent
6.9	2.17	3.95	18.2
7.4	2.20	3.96	18.0

(a) Pressed at 5000 psi.

(b) Sintered at 1510 C, 2 hours.

Strength test bars were similarly processed. The standard evaluations of the implants and test bars revealed the following:

- Sintered density and dimensional control were satisfactory. Wet-density measurements showed 14 randomly picked implants all to have densities of over 99 percent of theoretical, and to be on size.
- Microscopic examination in both reflected light and transmitted light (candling) revealed the presence of small white areas by the former technique and opaque spots by the latter technique. Their appearance was that of aggregates or granules of alumina which did not sinter to the fully-dense, translucent material, typical of well-sintered alumina. They were not widespread but still too common in about one-fourth of the implants made and in seven of the 12 strengths of the bars.
- Though some of the test bars showed adequate strength, others did not, the average value being unacceptable (51,000 psi). A correlation could not be established between the occurrence of the spots observed microscopically and the strengths of the bars.

A review of the results from this lot of implants and test bars showed two objectionable features. There was an inhomogeneity in many specimens in the form of the occasional white (opaque) spots that appeared as incompletely sintered aggregates in the otherwise normal translucent matrix material. There was also a considerable spread in strength. Correlation between the white spot occurrence and strength variation was not obvious. These features could be attributable to the fabrication processes or intrinsic to the lot of alumina.

Important to the sintering of the alumina to a dense translucent form is the presence of 0.05 percent of MgO which must be well distributed throughout the alumina. Aggregates of alumina powder without this MgO additive might sinter to form the white (opaque) spots observed. If this is the case, these spots are intrinsic to the lot of alumina received from the supplier. However, this phenomenon was not observed in previous fabrication efforts. The lot of alumina used was "old", having had the opportunity during its shelf-life to adsorb moisture from the air, which could affect sinterability.

Another source of the white spot could have been in the processing leading to the granulation of the alumina to obtain a free-flowing powder. In the processing step, rubber bags were filled with the as-received alumina and hydrostatically pressed at 10,000 psi, after which the pressed piece was crushed to pass a 40-mesh screen to give the free-flowing powder. The hydrostatically pressed shape was in the form of a cylinder nominally 75 mm in diameter and 75 mm long. This is a rather large volume for isopressing in one piece and the center of the slug very probably did not see the same pressure as the exterior. As a consequence, the granules resulting from crushing to pass the 40-mesh screen could have different densities and subsequently sinter at different rates. This could conceivably account for the white spots observed or the strength variation of the sintered bars.

On the assumption that the tooth roots and test bars were substandard because of aging characteristics of the alumina, the new lot of the Reynolds RC-HP-DBM alumina (designated No. 80-314) was transferred for storage into 1-gallon glass jars that were evacuated and back-filled with dry argon gas to enhance its shelf-life. In processing this new lot of alumina the first two steps described previously - hydrostatic pressing at 10,000 psi and granulation - were omitted. The as-received alumina was formed directly into preform rods by hydrostatically pressing at 50,000 psi. Forty-eight rods were formed, then bisque fired. This gave sufficient stock to make the desired tooth roots and strength test bars.

To evaluate the new lot of alumina and the processing up to this point, a quantity of test bars were ground from the bisque-fired rods. Ten were final sintered at 1540 C for 1-1/2 hours as before. All had strengths exceeding the minimum requirement, and their average strength of 75,000 psi was the highest that has been achieved on the program. The bars had wet-densities exceeding 99 percent of theoretical, and no inhomogeneities were observed on microscopic examination.

From the same bisque-fired stock from which these test bars were made, 45 tooth roots were ground to make three sets of roots of the sizes in Table 1. These along with additional strength test bars were sintered and inspected in the usual manner. Corresponding quality assurance tests (strength, density, and microstructure) were conducted.

The above mentioned unfortunate difficulties with producing ceramic implants delayed the project.

Mechanical Evaluation of Root/Crown Interface

One of the major areas of concern with the present root structure design has been the bond strength of the root/crown interface. The crown is fabricated as a two-part system. First, a gold alloy integral post and core is investment cast to fit each implant. After cementing the post in place in the mouth, impressions are taken and an all gold or porcelain veneer crown is fabricated to fit the post.

Two post and core designs are possible (Figure 1). In the first design the gold overlaps the outside of the root structure and extends downward into the gingival sulcus. The second design is formed flush with the exterior surface of the alumina. The prosthodontist prefers the use of the first design to maximize the strength of post/ceramic interface. The use of this design, however, necessitates setting the implant higher in the alveolar bone, which could impede the bone healing process. Also, the extended gold margin can irritate gingiva.

To resolve the need for the gold overlap, comparative strength tests were conducted on the two designs. Implants of matching size were prepared with posts of each design. The ceramic root was then imbedded into a cylinder of epoxy up to the top of the first or second serration. After curing, the implant was clamped into a horizontal fixture (i.e., root axis horizontal) and a lateral load was placed on the gold post using an Instron® Universal Testing Machine. The load was increased at a fixed rate until failure of the bond, gold, or ceramic occurred. The results of the test are summarized in Table 3.

TABLE 3. FRACTURE CHARACTERISTICS OF Laterally Loaded Post Design

Root Size mm	Post Design	Distance, Load Point to Fracture mm	Loading Rate m/min	Breaking Load, lb	Location of Break
6 x 8	Flush	6 mm	0.002	69	Second Serration
6 x 8	Overlap	5.5 mm	0.002	71	First Serration
6 x 9	Flush	6 mm	0.01	95	Second Serration
6 x 9	Overlap	6 mm	0.01	93	Second Serration
7 x 10	Flush	—	0.1	86	Recess Wall
7 x 10	Overlap	6 mm	0.1	98	First Serration

With one exception, all of the fractures were initiated through the ceramic at the height of the epoxy mount (i.e., at the base of the first or second serration). In all of these cases the gold core bent and pulled out of the lower section of the implant because of the levering action; the upper fractured section of the implant remained intact and securely bonded to the gold. The loads at fracture were essentially the same for implants of the same size. Since interface debonding did not occur above the fracture line, the tests serve to prove that the lateral load strength of the two different post designs are the same up to the worst case lateral load levels required to initiate implant fracture (70 to 100 pounds depending on implant size). Loads of this magnitude and direction are not expected under normal mastication. External impacts, however, could generate loads of sufficient nature to cause this type of failure. It would be interesting to compare the strength of natural teeth under the same mounting and loading conditions. However, the objective here was to verify the equivalency of restorative designs, thus allowing deeper implantation of the root structure. The deeper initial implantation should facilitate initial bone ingrowth by minimizing stresses.

A secondary result of this study is the implied need for further design studies. The fact that the ceramic failed before the attachment suggests that the interface design could and possibly should be modified to allow joint failure before ceramic failure. It certainly would be less traumatic to replace a failed crown and post then to surgically remove and replace a fractured root structure. Breakaway designs could also reduce peripheral facial and bone damage in case of accident.

Investigational Device Exemption Application

To place this study in compliance with 1976 modifications of the Pure Food Drug and Cosmetic Act, application for an Investigational Device was made to the FDA. This Exemption (IDE) allows clinical research of experimental devices that have not yet been commercially produced. The exemption provides necessary freedom for a product to be adequately evaluated. Strict reporting requirements are placed upon the investigators. The clinical data collected must be reported to the FDA at least annually. This exemption does not supplant the authority of the local human subject committee. The requested exemption was obtained for this project in January of 1981. Copies of the exemption application have been forwarded to the Army.

Baboon Implant Procedures

Animal implant procedures have been performed in the adult female baboon. Following extraction, the mandibular tooth socket, either molar or pre-molar, was shaped using a bone burr. A socket was formed by a continual fitting procedure. The root was firmly tapped into the alveolar bone until almost flush with the bone. The roots were given no further attention, except administration of prophylactic antibiotics immediately post-surgery and a soft diet for two weeks. The roots were observed periodically for three months. Radiographic examination and manual palpation indicated if the root was

adequately stable for reconstruction. A similar procedure was used to implant roots in edentulous sites.

Restoration of the implants was facilitated by prefabrication of a gold post and core prior to implantation. Following adequate stabilization by bone ingrowth into the serrations (at approximately 3 months), the post and core was cemented into place. Impressions were taken. A gold crown was fabricated and cemented into place. Care was taken to provide correct occlusion.

The implant is periodically examined and documented by radiographs and photographs. Clinical chemistry, hematology, and parasite analyses are performed at the same intervals.

It should be noted that most baboon roots were implanted prior to the time period covered by this report.

Baboon Husbandry

The nine animals being evaluated are individually caged in one room of the Battelle-Columbus animal facility. The animals are fed Purina monkey chow twice daily. One daily meal consists of the chow pre-moistened and softened whereas the other meal is the same chow in the as-received dry state. Water is ad libitum via drinking pans. The room environment is maintained on a 12-hour light/12-hour dark cycle. Temperature is maintained between 72-76 F. Humidity is maintained between 40-60 percent RH. Visual observations of the animals are recorded twice daily. Any unusual observations are reported to the veterinarian in charge and the principal investigator. For evaluation procedures, the animals are tranquilized with Ketamine® prior to removal from their cages.

Human Implant Procedures

Rectangular implants are placed in edentulous or fresh extraction sites typically in mandibular molar or premolar sites. Roots are placed where they will function as single free-standing implants when reconstructed. Under local anesthetic, implant sites are prepared using bone burrs placed in a low-speed contra-angle air turbine handpiece with sterile saline cooling. A continual fitting procedure is used. Final placement of the implant is via tapping with a mallet to provide a stable interference fit. The roots are observed visually and radiographically throughout the study. Normally a gold post and core is prefabricated for each implant. The patients are observed periodically until the implant is rigid or exhibits minimal motion. At that time the post and core is cemented, and a clinical crown fashioned. Periodic examination of the patient continues following reconstruction. All clinical studies are performed at The Ohio State University College of Dentistry in compliance with a protocol approved by the University human subjects committee and the FDA Bureau of Medical Devices.

Three variations of implant technique have been employed: In the first group, implants were surgically placed so that the uppermost serration is just covered by the crest of the alveolar ridge. Consequently, about 3 mm

of implant were left protruding above the ridge. The first 25 patients were implanted in this fashion.

A second group of six patients' implants were prepared with integral post and cores. The implants were partially isolated from occlusal loads by orthodontic stay wires attached to adjacent dentition and a methacrylate resin cap over the top of the implant.

A third group of eight patients was prepared in which the top of the root was placed flush with the alveolar crest. Additionally, in seven of these patients, a muco-periosteal flap was placed over the top of the implant.

RESULTS

Animal Studies

During the last year, long-term observation of implants has continued in nine baboons. Again, as was observed in previous years, the failure rate has been low. Presently 34 roots are being followed in the baboons. Twenty-six of these roots have been reconstructed and are now "successfully" in function. In the last 5 years, 4 roots have fractured after reconstruction. Three fractured roots were of the elliptical design and one of the rectangular design. All of the fractured implants were made in 1976. Two of the fractures occurred at 2+ years of function; one at approximately 1 year of function and one at 3 months of function. The cause of the fracture is not known. However, these particular roots were produced from lower strength alumina than that presently being used. The apical portion of these roots are still firmly anchored in alveolar bone. Another root failed when placed into function 2 months post surgery. It still remains mobile after 4 years. This root is being followed to assess the fate of mobile implants. After 2 years, crown height was reduced on this root to decrease its function. The root has not become inflamed nor is it mobile enough to allow easy removal. Bone ingrowth has been sufficient to provide retention. Apparently, mobility has promoted the generation of connective tissue. There does not appear to be a continued loss of alveolar bone.

Roots in function are considered "successful" by the following criteria:

- (1) Radiographic appearance of dense bone ingrowth into serrations
- (2) Resistance to movement by manual palpation (rigid)
- (3) Minimal gingival irritation
- (4) Maintenance of occlusion.

Roots which have remained rigid but have not been put into function are termed "potentially successful" until they are reconstructed. All "successful" roots in this study were implanted a minimum of 3 months before reconstruction.

In the 9 animals still being observed, the following history of functional success has been observed to date:

<u>Number of Roots</u> <u>(in all 9 Baboons)</u>	<u>at</u>	<u>Approximate Time</u> <u>in Function, yrs</u>
4		5-1/2
2		4
14		3-1/2
3		2
3		1
Total	<u>26</u>	

When the five failed implants are considered (4 fractures, 1 lost post and core), a total of 26 functional roots are still under study. When the implant history for the nine baboons still in the colony is traced back to the beginning, an overall failure rate of 10/39 or 26 percent is observed. As previously noted, most of the failures occurred immediately following implantation. Five of these pre-reconstruction failures were with elliptical design implants in fresh extraction sites. No rectangular or healed sites have failed. The major mode of post reconstruction failure is fracture of the ceramic at the alveolar crest. Failure rate has remained low compared to our earlier animal studies where failure rates during the first three months were 40 percent.

In the 9 animals now being observed, the total post-implant time for roots is (this includes all ceramic which is rigid but not necessarily in function):

<u>Number of Roots</u>	<u>at</u>	<u>Approximate Time Since Implant (Including Nonfunctional Time Prior to Reconstruction), yrs</u>
4		6
2		4-1/2
21		4
4		3
3		1
Total	<u>34</u>	

To obtain these 34 remaining implants, 39 were implanted. Twenty-six were elliptical roots, 23 in fresh sites of which 18 remain, 3 in healed sites of which 3 remain. Thirteen rectangular roots were placed (nine in fresh sites and four healed sites) all of which remain.

Gingival irritation, however minimal, is a drawback of this implant in the baboon. The minor irritation appears to be related both to the approximation of gold to the gingival tissue as well as to the relatively poor oral hygiene of the baboon. Infection has never been a causative factor in the loss of an implant. Apparently, the environment in the oral cavity allows the implant to survive even though there is no attachment of gingiva to the ceramic root. (Fortunately, the gingival irritation present in baboons is not seen in humans). Histologically, gingiva is observed invading the upper most serration. In the majority of these implants, attachment of gingiva to the surrounding alveolar bone has been maintained.

Figure 2 shows two implants in function for 2-1/2 years. These implants are still successful by the indicated criteria. The band of gingival tissue is seen in multiple implants, most probably caused by some loss of bone-gingiva attachment. Figure 3 shows a radiograph of the same implants as shown in Figure 2. Ingrowth of bone is apparent. There has been some vertical loss of bone, however bone height appears stable at the present level. Figure 4 shows the same implants 3 months post-implant and Figure 5 is a radiograph of the implants at the same time as in Figure 4. Notice that the gingival health is excellent at this time. Bone ingrowth appears to have



FIGURE 2. RESTORED IMPLANTS IN A 29 AND A 30 OF BABOON 710. THESE TWO FREE-STANDING IMPLANTS WERE IMPLANTED FOR 2 YEARS 10 MONTHS AT THE TIME OF THIS PHOTOGRAPH. THE IMPLANTS HAVE BEEN FUNCTIONAL FOR 2 YEARS 4 MONTHS. THESE IMPLANTS ARE RIGID. MILD GINGIVAL INFLAMATION IS PRESENT. THIS INFLAMATION IS COMMON IN BABOON IMPLANTS.



FIGURE 3. RADIOGRAPH OF IMPLANTS IN FIGURE 2 AFTER 3 YEARS OF FUNCTION. NOTE THAT THE DENSITY OF BONE OBSCURES THE SERRATION DETAIL COMPARED TO FIGURE 6 AT TIME OF IMPLANT. THIS LOSS OF SERRATION DETAIL IS USUALLY NOTED IN CASES WHERE THE IMPLANT HAS BECOME TOTALLY RIGID. THIS PHENOMONA IS ALSO SEEN IN HUMANS. (FOR EXAMPLE FIGURE 8 IN THIS REPORT). ALSO NOTE SOME LOSS OF ALVEOLAR BONE HEIGHT. APPROXIMATELY 2mm OF BONE HAS BEEN LOST SINCE THE TIME OF SURGERY.



FIGURE 4. BABOON IMPLANTS FOUR MONTHS POST SURGERY IN ANIMAL 710.

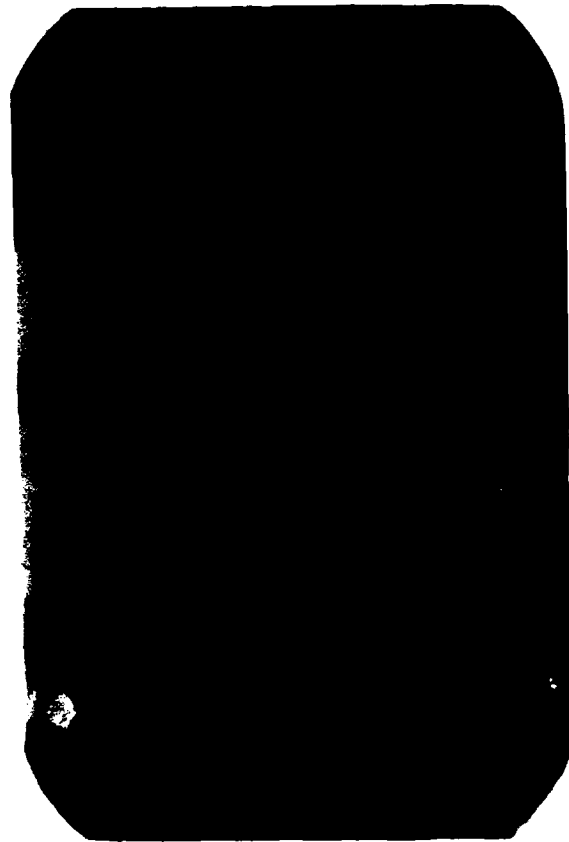


FIGURE 5. RADIOGRAPH OF BABOON 710, 1 MONTH POST IMPLANT. NOTE THE APPEARANCE OF BONE ABOUT THE SERRATIONS AS COMPARED TO FIGURE 6.

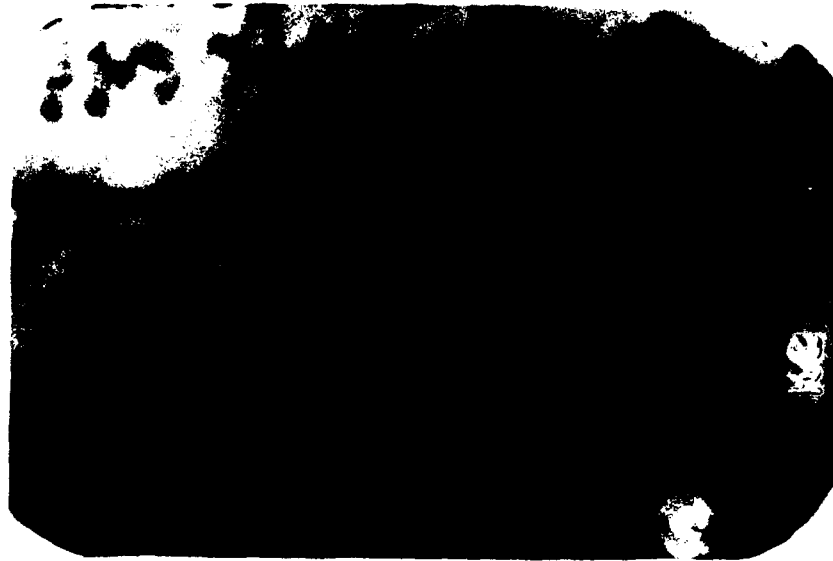


FIGURE 6. RADIOGRAPH OF BABOON 710 AT TIME OF SURGERY. NOTE LACK OF BONE ESPECIALLY IN THE MESIAL (RIGHT) IMPLANT. WHEN COMPARED TO FIGURE 5 IT CAN BE NOTED THAT SOME ALVEOLAR BONE IS LOST WITHIN THE FIRST MONTH, POST SURGERY.

occurred into the serrations. By comparison with a radiograph at the time of surgery (Figure 6) the bone ingrowth and increase in bone density with time can be observed.

Clinical Chemistry and Hematology Results in Baboons

Throughout the project history hematology and clinical chemistry data have been collected on all animals at approximately 3 month intervals. The data for all animals has been compared to control (pre-implant) data. To date no value has shown a significant alteration from baseline. The parameters measured are: Glucose, BUN, Chloride, Bilirubin, Alk. phos., SGOT, SGPT, Creatinine, Na, Ca, Mg, K, Hemoglobin, Hematocrit, WBC, RBC, MCV, BANDS, SEGS, EOS, BASO, Lymph, Mono, Platelets, Retic and Pro-time.

Clinical Studies

The clinical portion of this project has involved the implantation of rectangular ceramic roots in 40 patients. The clinical study commenced in August, 1978. The roots have been implanted using three different techniques. In the first 25 patients, roots were implanted with the first (or uppermost) serration flush with the alveolar crest. This implant height was dictated by the post and core design. The gold coping of the core extended over the top of the implant. In the human, the implant was placed high enough to allow post and core seating without bone removal. Hence the implant was placed higher than in baboon studies. The high success rate in baboons, even when the implants were left to protrude slightly above the alveolar bone level, gave us confidence that in the "cooperative" human subject this procedure would be acceptable. In the first 25, mandibular molar and premolar sites were used. Seventeen were healed sites and 8 were fresh extraction sites. All implants were periodically observed by clinical observation and X-ray. All implants were rigid at the time of surgery by virtue of the interference fit produced by tapping the implant into place. All implants exhibited some degree of buccal-lingual mobility within the first 1 to 3 months post-implant. The degree of mobility and the cause of the increase in mobility was highly variable but typically 1/2 mm or less mobility was observed within that time period. Sixteen of the 25 patients exhibited a subsequent decrease in mobility with time. Ten of the 25 patients can still be considered to be successfully implanted. One patient has been lost to the study (left town). Another patient has not been available for reexamination for one year. The remaining successful patients all exhibit between 0 and 1/2 mm of buccal-lingual mobility. The average time in function is 1 year, 24 weeks (+17 weeks). The oldest implant has been in function 2 years.

The typical failure process observed is a slow increase in mobility over a period of 1 to 2 years. When mobility reaches 1 mm buccal-lingual with rotation present, the implant is removed to prevent unnecessary bone loss. Average implant life until failure or preventive removal was 1 year, 38 weeks (+38 weeks, N = 15). Two patients had infection noted at the time of removal.

Seven patients near removal time indicated some degree of soreness when biting hard. Generally gingival health remained excellent in all patients regardless of the state of failure. Most patients utilized the implants as functional and aesthetic devices up until the time of removal. Several patients had to be convinced of impending implant failure since they were satisfied with the devices.

The successful implants in this group were those in which the progression of mobility reversed itself and the bone height remained stable. Figures 7 through 9 show the history of a totally successful implant in which the progression of mobility reversed and the implant became totally rigid, with no evidence of connective tissue. Figure 7 shows a post-surgical radiograph. The serrations of the implant are clearly visible as is the large bone void from the extraction. Figure 8 shows the same implant approximately 20 months later (functional for 42 weeks). Note there has been minimal bone loss at the alveolar crest. The serrations of the implant are not clearly visible probably due to increased bone density about the serrations. This radiograph is identical to that which can be observed in a successful long-term baboon implant. Figure 9 is a clinical view of the same implant after 16 months of function (26 months post-implant). This particular implant is totally rigid and successful by all criteria.

A more typical "successful" implant in the initial group of 25 is illustrated by Figures 10 through 12. Figure 10 shows the radiograph of the implant at surgery. Note the serrations are easily visible. The implant is placed high, relative to the alveolar ridge. This implant height relative to alveolar bone is representative of this group of patients. Figure 11 is a radiograph of the patient at 1 year 9 months post surgery; note that the serrations are still visible. Approximately a 5 mm loss of vertical bone height has occurred. A small line of radiolucency is present at the bone ceramic interface. This patient exhibits a very slight mobility of less than 1/4 mm. Presumably there is a connective tissue interface. Figure 12 is a clinical view of the same patient 2 years and 8 months post-implant and 11 months of function. This patient is functional and pain-free. However, the implant is not as satisfying as the previous example. Total rigidity of the implant would be necessary to provide an ideal result.

Figures 13 through 16 represent the history of an implant that went on to failure. Figure 13 shows a radiograph taken at surgery and Figure 14 the clinical view at 7 months post-surgery. This particular implant was never completely stable. Figure 15 shows the clinical situation at 1 year of function (2 years post-implant). The implant appears deceptively healthy in this view. However, Figure 16 shows a radiograph at 18 months post-implant (3 months function). Note already the loss of vertical bone height at least 5 mm and the radiolucency about the serrations. This implant was subsequently removed due to 1 mm buccal-lingual mobility and rotation. The removal was to prevent unnecessary bone loss. Post-removal examination of patients at 3 to 6 months typically shows normal healing with filling of the bony void in a manner similar to that seen post-extraction.

In view of the difficulty of obtaining stability in the first group of patients, the next series of six patients were performed using orthodontic devices to stabilize the implant to adjacent teeth. Orthodontic bands were fitted to adjacent teeth and connected by wires. An acrylic cap was fitted over the top of the implant to support and protect the implant.

The patients were implanted in the posterior mandibular areas, 5 in healed sites, and 1 fresh extraction site. The fresh extraction site implant



FIGURE 7. RADIOGRAPH AT TIME OF SURGERY FOR HUMAN PATIENT IMPLANTED IN A FRESH EXTRACTION SITE A 30. NOTE THE IMPLANT WAS PLACED WITH AT LEAST 3mm OF CERAMIC ROOT PROTRUDING ABOVE THE ALVEOLAR CREST.



FIGURE 8. RADIOGRAPH OF IMPLANT (SAME AS FIGURE 7) AFTER 42 WEEKS IN FUNCTION. TOTAL IMPLANT TIME 1 YEAR 8 MONTHS. NOTE LOSS OF SERRATION DETAIL WITH TIME, HOWEVER NOT AS CONVINCING AS WITH THE BABOONS. ALSO NOTE APPROXIMATELY 2mm OF BONE LOSS FROM THE ALVEOLAR CREST. THIS IS A TOTALLY RIGID IMPLANT.



FIGURE 9. CLINICAL APPEARANCE OF PATIENT SHOWN IN FIGURE 7 AND 8 AFTER 1 YEAR 4 MONTHS OF FUNCTION. (2 YEARS 2 MONTHS TOTAL IMPLANT TIME).



FIGURE 10. HUMAN PATIENT RADIOGRAPH AT TIME OF SURGERY. THE IMPLANT WAS PLACED IN A FRESH EXTRACTION SITE A 19. NOTE THE IMPLANT WAS PLACED CONSIDERABLY ABOVE THE ALVEOLAR CREST.

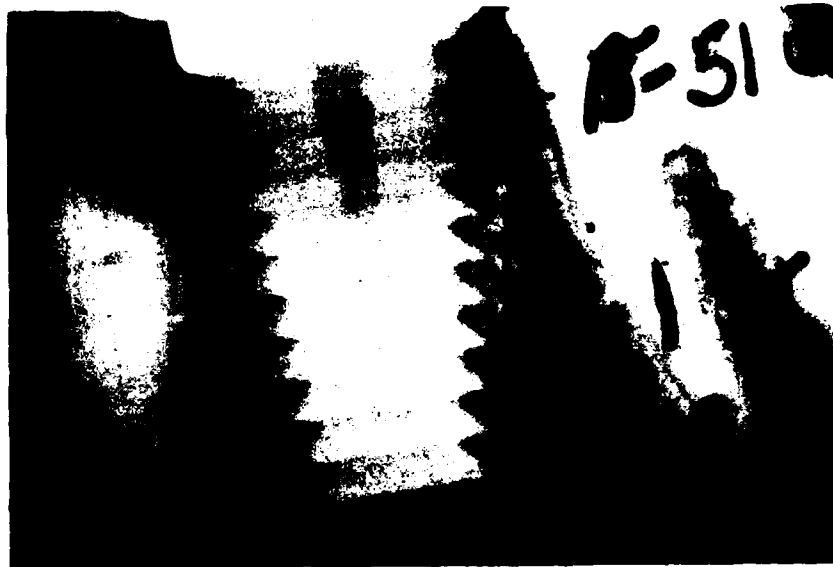


FIGURE 11. RADIOGRAPH OF IMPLANT IN FIGURE 10, 1 YEAR 9 MONTHS AFTER SURGERY AND 1 YEAR POST RESTORATION. NOTE VERTICAL BONE LOSS AND THIN LINE OF RADIOLUCENCY ABOUT THE IMPLANT. THIS POST EXHIBITS LESS THAN $1/4$ mm OF MOBILITY.



FIGURE 12. CLINICAL VIEW OF PATIENT IN FIGURE 11 AT 1 YEAR POST RESTORATION.



FIGURE 13. RADIOGRAPH OF IMPLANT IN FRESH EXTRACTION SITE (A19)
AT TIME OF SURGERY.



FIGURE 14. CLINICAL VIEW OF IMPLANT SHOW IN FIGURE 13, 7 MONTHS POST SURGERY.

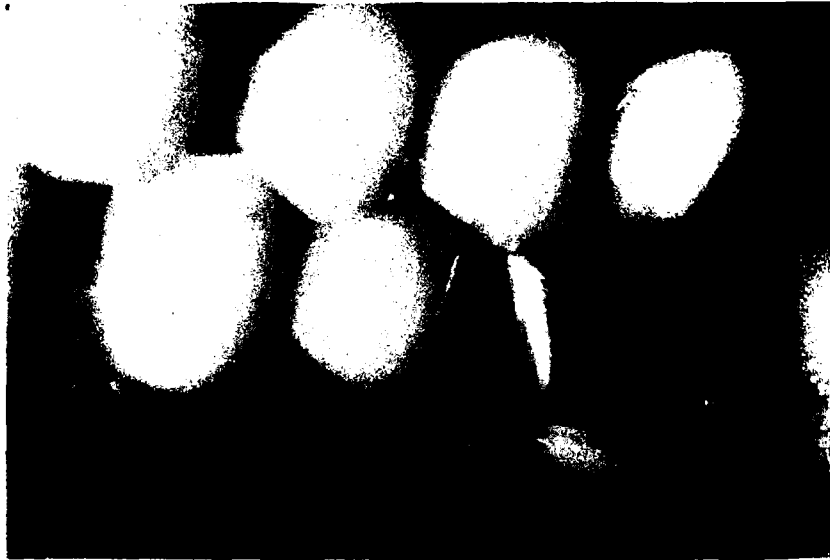


FIGURE 15. CLINICAL VIEW OF PATIENT IN FIGURES 13 AND 14, 2 YEARS AFTER SURGERY AND 1 YEAR AFTER RESTORATION. THE IM-PLANT APPEARS DECEIVINGLY HEALTHY. UNFORTUNATELY IT WAS EXTRACTED THE DAY OF THIS PICTURE DUE TO EXCESS MOBILITY.



FIGURE 16. RADIOGRAPH OF IMPLANT IN FIGURE 15. THIS IMPLANT IS FAILING DUE TO ITS EXTREME LOSS OF VERTICAL BONE HEIGHT. AS WITH ALL FAILED IMPLANTS, INITIAL STABILITY WAS NOT MAINTAINED.

never stabilized and was never restored. The implant was removed at 35 weeks post-surgery when rotation was observed. The five healed site implants have remained and all have been placed in function; however, all exhibit some degree of mobility. Between 1/2 or 3/4 buccal-lingual mobility is typically observed. These five roots have been in function an average of 19 weeks (+4 weeks). Total implant time for these implants averages 51 weeks (+5 weeks). Even though the apparent success rate is higher than the previous group, the overall result is still less than satisfactory since there is some degree of mobility noted in all of these roots. Reduction in mobility (after the initial loosening) has not been noticed in any of these roots as was the case in some of the prior implants.

A third group of patients termed the deep implant placement group was undertaken. This group was to assess if a deeper placement of the root would offer the additional protection from mechanical stress to provide initial stabilization.

The previously mentioned mechanical tests illustrated that the post and core could be modified to allow a deeper placement. The removal of the gold overlap (or coping) was shown to not reduce the mechanical strength of the root-post and core attachment. Consequently post and cores were made without a coping protruding downwards over the outer edge of the alumina root. This modification allowed the alumina root portion to be placed flush with the alveolar crest. Eight patients were implanted with the top of the root flush with the alveolar crest. Figure 17 is an example at surgery of a flush implant. One implant was in a fresh extraction site. The remainder were in healed sites. In seven of the patients, the implant was covered with a muco-periosteal flap. In five of these seven patients, the implant site partially denuded. In two of these five patients the implant site was recovered with gingival tissue by an additional surgical procedure. These implants have now been followed for an average of 12 weeks (+4 weeks). (The longest is 16 weeks). Upon reexamination, all implants were found rigid at all examinations and little or no bone loss was noticed radiographically. It appears that the implants have never loosened. This observation is significant since some degree of mobility has been noticed usually starting between 1 and 4 weeks in roots implanted by the two previously described techniques. This method appears to provide initial stability in a manner similar to that seen in baboons.

It should be noted that stability throughout the ingrowth period was found in baboons to be a key factor to the long term success of the implant. The subsequent implants scheduled in the present series will be implanted using the flush technique.



FIGURE 17. CLINICAL VIEW OF IMPLANT PLACED FLUSH WITH THE ALVEOLAR RIDGE AT THE TIME OF SURGERY. ALL IMPLANTS IN THIS GROUP ARE POTENTIALLY SUCCESSFUL. NONE HAVE LOOSENED SINCE THE DAY OF SURGERY. THE DEEP PLACEMENT PROVIDING GREATER ISOLATION FROM MECHANICAL STRESSES THAN PREVIOUSLY USED METHODS IS ASSUMED RESPONSIBLE FOR THE DRAMATIC IMPROVEMENT IN THIS LATEST GROUP OF IMPLANTS.

CONCLUSIONS AND RECOMMENDATIONS

The animal research to date indicates a high probability of success for the implant system. Loss of stability via bone loss or infection has not occurred in any animal implant that has become stable. Current failures in baboons have been caused by fracture of ceramic at the approximate level of the alveolar crest. Fractures appear to be clustered in implants produced in 1976. However, the definitive reason for the fractures is not known.

The baboon continues to provide valuable information as to long-term success of implants. The longest term implants provide proof that successful function of serrated ceramic implants is possible for up to six years. There has been no evidence of any deleterious effect of the implant upon the health of the animal by any of the indices measured.

This baboon colony is a unique research resource in that it is the only known long-term animal trial on ceramic implants. The clinical chemistry, clinical health, and eventual necropsy data (both gross and microscopic) will be relevant to the human situation. One apparent drawback to the baboon model is the ease and rapidity of bone ingrowth relative to the human. However, once ingrowth has occurred, the baboon model provides a "worst case" test for the implant. Relatively high loadings and a lack of oral hygiene are a severe test for the implants.

The human studies initially did not prove as successful as the baboon studies. Loss of initial stability of the implant appears to effect the long-term success. Even though all human implants were implanted stable by virtue of an interference fit with the bone, this stability was lost within the first month. In the successful cases, the relative degree of stability reversed and continually decreased until minimal. However, in many of the implants, stability slowly increased over a period of 1 to 2 years until failure was inevitable. In light of the loss of initial stability, different stabilization techniques were attempted to rectify the situation. The most recently employed technique of placing the implant flush with alveolar bone has produced a dramatic change in the results. The extra isolation from mechanical stresses appears to have made a significant difference since stability has not been lost in any patient in the initial phases of ingrowth. This initial ingrowth was found to be crucial in early baboon experiments.

The initial implants in patients were not placed flush with the bone, since the overlapping gold core prevented the deep placement. In animals it was quite acceptable to remove alveolar bone to place the post and core, but such a practice was not considered proper in human patients. Also the higher placement of implants did not appear deleterious to the success rate in baboons. These two factors led to the original decision to place implants higher relative to the alveolar crest in humans. When stability was being lost in humans, mechanical tests on modified post and core showed that the outer coping could be eliminated without a loss of strength. Consequently, the most recent group of patients with the flush implant were undertaken. We believe that this modification in technique can provide a success rate similar to that observed thus far in baboons.

It is recommended that the study be continued in humans using the flush implant technique. These implants will be placed as single freestanding devices. The baboon colony should be continued until the average implant has

been in function at least 5 years. The presently utilized method of manufacture should be continued since it has proven successful. A careful analytical analysis of small-sized implants should be performed to assure that adequate mechanical strength is being provided by the implant structure to withstand reasonable occlusal loads with an adequate margin of safety.

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QUALITY ASSURANCE STATEMENT

This study was inspected by the Quality Assurance Unit and reports were submitted to management and the principal investigator as follows:

<u>Phase</u>	<u>Date</u>
Body Weights	3/19/81
Temperatures	3/19/81
Rectal Swab	3/19/81
Tuberculosis Test	3/19/81
Implant Exam - Clinical Observation	3/19/81
Radiograph and Clinical Photographs	3/19/81
Blood Collection	3/19/81
11th Annual Report Review	8/10/81

To the best of my knowledge the methods described were the methods followed and the data presented accurately represent data generated during the study.



Ramona Mayer, Director
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